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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,766	11/26/2003	Klaus Klingenbeck-Regn	P03,0471	9678

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EXAMINER	
LAMPRECHT, JOEL	
ART UNIT	**PAPER NUMBER**
3737	

MAIL DATE	DELIVERY MODE
10/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/723,766	KLINGENBECK-REGN ET AL.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-15,17 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7-15, 17, 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7-15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pitris et al (US 6,564,087 B1) in view of Strommer et al (US 2002/0049375 A1) and in further view of Hastings et al (US 2002/0103430 A1). Pitris et al disclose the use of an OCT image catheter for introduction into the body including OCT fiber bundling for image acquisition and guidance, the OCT catheter including fibers adapted to image in a rotational scanning pattern (Col 11 Line 35-Col 12 Line 20),

and the system is described as being integrated with an imaging system such as either an x-ray system or an MR imaging system for guidance and control.

Pitris et al do not disclose the specific integration methods of an x-ray imaging system with their system, nor do they disclose the use of a medical-field generating element disposed in the tip of the catheter system for interacting with the catheter control device in order to control motion of the catheter relative to the examination region.

Attention is first directed to the secondary reference by Strommer et al which discloses an OCT catheter system in conjunction with an x-ray guidance system and processing system which allows for monitoring of the OCT catheter (Col 5 Line 1-58) as well as superimposed image display of the OCT image and x-ray image to control the movement of the catheter in the patient (Col 26 Line 10 – Col 27 Line 25). The x-ray system in conjunction with the OCT system of Strommer et al additionally allow for processing of the x-ray and OCT images by the same processor (Col 25 Line 60- Col 26 Line 10) and then superimposing them using a superimposing processor (Col 5 Line 1-41, Col 26 Line 10- Col 27 line 25 and Col 40 Line 5-55), include a imaging and navigation system for control of the catheter system (Col 6 Line 15-62), as well as an MPS system which includes the use of magnetic-field generators located both on the external imaging system (Col 17 Line 45- Col 17 Line 15, Col 29 Line 54-Col 30 Line 20) as well as disposed within the catheter system itself for the control and guidance of the catheter element within the body (Col 14 Line 65-Col 15 Line 35). The teaching reference by Strommer et al, while focused on the MPS system and the electromagnetic

fields generated and detected by the electromagnets and detectors is silent about the construction of the system, the relative position of the elements, and the directions of the fields generated thereby.

Therefore, attention is also directed to the secondary reference by Hastings et al for the purpose of teaching the placement of the electromagnetic field-generating element in the tip of the catheter (0009) to control and generate an electromagnetic signal measurable by the system (0041 figure 7), and uses multiple magnetic elements (figure 3, 0007-0009 0041), and multiple normal directional coiling (0013-0014) to generate fields in multiple perpendicular directions to the catheter in order to control the electromagnetic fields both generated and received (0038, 0043-0044). The magnet so disposed within the tip (0002) is a permanent magnet, and the procedure uses diagnostic information from an imager (in this case an MRI imager as denoted as suitable in the Strommer et al and Pitris et al references) in order to enhance the control of the catheter element through the body and acquire further imaging data. It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the electromagnetic guidance system (including locations and directional teachings) of Hastings et al with the MPS/OCT guidance system of Strommer et al and the OCT catheter system of Pitris et al for the purpose of facilitating a detailed integrated medical imaging diagnostic procedure of a patient where accurate guidance and integrated imaging create the best diagnostic data for treatment of a patient.

Response to Amendment

Applicant's arguments filed 7/8/08 have been fully considered but they are not persuasive. Regarding Applicant's argument to combine, it is acknowledged that the motivation which is listed is indeed the overall motivation driving the combination of the references, and finds its basis for the combination within each respective reference. The fact that the references are in the medical imaging field is only the starting point of the 103 analysis as mentioned within the response, and the motivations to combine lie in the recitation of the disclosures themselves. The Pitrus et al reference recites from Col 18 Line 54- Col 19 Line 10 that guidance and placement of the device are assisted with ultrasound or MR images for the purpose of facilitating real-time guidance and placement of the probe or catheter with OCT to allow for image-based diagnosis. The Strommer et al reference then recites and additionally teaches that using an OCT system in conjunction with an MPS system allows for the control and tracking of the catheter inside the human body, including specific focus on the tip of the catheter for the purpose of acquiring an accurate representation of the orientation of the catheter within the body (and for imaging with OCT) (Paragraphs 129, 199-202, 205-210). Finally, the Hastings et al reference supplies the motivation for the localization of a tip of a catheter with an EM field generating element disposed within the tip (0002, 0007-0009, including the use with endovascular imaging methods and specific prior art motivations including those which include coils in the tip which are used to located the tip and measure orientation within three-dimensions (bottom of paragraph 0008)). For these reasons, one of ordinary skill within the art would use the combination of references for the

greater motivation of facilitating detailed integrated imaging diagnostic procedures is accomplished in situations where accurate catheter navigation allow for the best diagnostic image of a patient, not Applicant's disclosure, as argued.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/BRIAN CASLER/

Supervisory Patent Examiner, Art Unit 3737